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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,192	07/14/1999	ALAN GEORGE BAXTER	229752000600	5844

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/308,192

Applicant(s)

BAXTER, ALAN GEORGE

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8-19 and 22 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 11-19 and 22 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-10 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 May 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Request for Continued Examination

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's submission filed on 09/15/04 has been entered.

Applicant's Amendments

2) Acknowledgment is made of Applicant's amendments filed 03/16/04 and 09/15/04 in response to the final Office Action mailed 09/16/03.

Status of Claims

3) Claim 1 has been amended via the amendment filed 03/16/04.
Claim 1 has been amended via the amendment filed 09/15/04.
Claims 1, 8-19 and 22 are pending.
Claims 1 and 8-10 are under examination.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

The Unsigned Baxter Declaration

6) Acknowledgment is made of Applicant's submission of the Baxter Declaration filed 09/15/04. The Declaration has not been signed and therefore the contents therein have not been considered. Applicant states that a signed copy of the Declaration would be provided once received. Until the issuance of this Office Action, the Office has not received the signed version of the Declaration. A telephonic attempt to obtain the signed version of the Baxter Declaration via facsimile in November 2004 was unsuccessful.

Rejection(s) Withdrawn

- 7) The rejection of claim 1 made in paragraph 15(a) of the Office Action mailed 09/16/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.
- 8) The rejection of claim 1 made in paragraph 15(c) of the Office Action mailed 09/16/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

Rejection(s) Maintained

- 9) The rejection of claims 1 and 8-10 made in paragraph 7 of the Office Action mailed 02/26/03 and maintained in paragraph 12 of the Office Action mailed 09/16/03 under 35 U.S.C. § 112, first paragraph, as being non-enabling with regard to the scope, is maintained for reasons set forth therein and herebelow.

Applicant submits that Examples 10 and 11 describe the use of heat killed *Mycobacterium bovis* (BCG) from which *Mycobacterium* subfractions were obtained. Applicant states that they would submit a signed copy of the Baxter Declaration which provides additional data showing that MAPG from two representative strains of *Mycobacterium*, *Mycobacterium bovis* and *Mycobacterium tuberculosis* prevented the development of type 1 diabetes, and showing that a sub-component of MAPG, APG, provides protection against type 1 diabetes.

Applicant's arguments have been carefully considered, but are not persuasive. The Baxter Declaration is an unsigned document, which has been placed in the case, but has not been considered. Claim 1 still includes within its scope the broad limitations, 'a component of MAPG' and '*Mycobacterium*'. The recited 'MAPG' is not purified and therefore, the limitation 'a component of MAPG' encompasses components of unlimited or unspecified size and nature, the structure of which components has not been described within the instant specification, as originally filed, for one to make them and use them in the claimed method. The anti-diabetic immunomodulatory ability of these unlimited MAPG components has not been demonstrated. The rejection stands.

- 10) The rejection of claim 1 made in paragraph 11 of the Office Action mailed 02/26/03 and maintained in paragraph 13 of the Office Action mailed 09/16/03 under 35 U.S.C. § 102(a) as

being anticipated by Stosic-Grujicic *et al.* (*Mikrobiologija* 33 (1): 27-36, 1996), is maintained for reasons set forth therein and herebelow.

Applicant argues that Stosic-Grujicic's TDM and PPD are not equivalent to MAPG. Applicant states that MAPG has been well characterized in the art to be an insoluble complex consisting of peptidoglycan linked to polysaccharide side chains, which chains have mycolic acids esterified to the distal ends of the polysaccharide side chains. Applicant submits that MAPG is a complex consisting of lipids, sugars and peptides, whereas PPD consists of a number of secreted soluble proteins. Applicant contends that PPD is not part of the bacteria's cell wall and that TDM are extractable glycolipids and are a member of the mycolic acid family. Applicant states that TDM and other lipids are removed from MAPG during the extraction process.

Applicant's arguments have been carefully considered, but are not persuasive. Claim 1, as amended, still includes the limitation 'a component of MAPG'. The MAPG as recited in the claim is not required to be 'purified', which means it contains lipid, protein, peptide and/or polysaccharide impurities or contaminants. These impurities are not excluded as components of an unpurified or isolated MAPG, but are included. A single amino acid contained in the prior art PPD or a piece of a lipid contained in the prior art TDM meets the limitation 'a component' of an isolated, but unpurified MAPG. Since the exact structural composition of the 'a component of MAPG' isolated from the cell wall of *Mycobacterium* is not described, Stosic-Grujicic's well-defined immunomodulatory mycobacterial components derived from the cell wall are viewed as containing such a 'component of MAPG', and therefore are able to bring about the same therapeutic effect against diabetes as that of the Applicant's product. The rejection stands.

11) The rejection of claims 1 and 10 made in paragraph 12 of the Office Action mailed 02/26/03 and maintained in paragraph 14 of the Office Action mailed 09/16/03 under 35 U.S.C. § 103(a) as being unpatentable over Stosic-Grujicic *et al.* (*Mikrobiologija* 33 (1): 27-36, 1996), is maintained for reasons set forth therein and above.

12) The rejection of claims 1 and 9 made in paragraph 15(b) of the Office Action mailed 09/16/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein with regard to the limitation: 'component of MAPG'.

13) The rejection of claims 8-10 made in paragraph 15(d) of the Office Action mailed

09/16/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

14) Claims 1 and 8-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant(s) regards as the invention.

(a) Claim 1 is vague and fails to distinctly claim the subject matter in the phrase: ‘method of immunomodulatory therapy in mammal wherein the immunomodulatory therapy is for the treatment of insulin-dependent diabetes mellitus (IDDM)’. For the purpose of distinctly claiming the subject matter, it is suggested that Applicant replace the recitation with --method of immunomodulatory treatment of insulin-dependent diabetes mellitus (IDDM) in a mammal-- and delete the limitations in the last two lines of the claim: ‘wherein the immunomodulatory therapy is for the treatment of insulin-dependent diabetes mellitus (IDDM)’.

(b) Claim 8 lacks proper antecedence in the limitation ‘MAPG’. Claim 8 depends from claim 1, which already includes the recitation ‘MAPG’. Therefore, for proper antecedence, it is suggested that Applicant replace the limitation with --said MAPG--.

(c) Claim 9 lacks proper antecedence in the limitation ‘MAPG or a component thereof’. Claim depends from claim 1, which already includes the recitation ‘MAPG or a component of MAPG’. Therefore, for proper antecedence, it is suggested that Applicant replace the limitation with --said MAPG or said component thereof--.

(d) Claim 1 is confusing and/or redundant in the recitations: ‘mycolyl arabinogalactin peptidoglycan (MAPG) component of mycolyl-arabinogalactan-peptidoglycan (MAPG)’. It is further unclear how an ‘arabinogalactin’ and an ‘arabinogalactan’ containing substance can both be referred to as MAPG. It is suggested that Applicant replace the recitations with --mycolyl-arabinogalactan-peptidoglycan (MAPG) component of MAPG--.

(e) Claims 8-10, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

15) Claims 1 and 8-10 stand rejected.

16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.

17) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

18) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

December, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER